

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Houghton, et al.	
Application No.: 09/996,128	
Filed: 11/27/2001	Group Art Unit: 1643
Title: Compositions for Treatment of Melanoma and Method of Using Same	Examiner: A Harris
Attorney Docket No.: MSK.P-026-3	

REPLY BRIEF FOR APPELLANT

This reply brief is filed in support of Applicants' Appeal from the final rejection mailed 12/27/2006, and in response to the Examiner's Answer mailed November 28, 2007.

On Page 4 of the Examiner's Answer, the Examiner states that Applicants argument is the applied reference is not applicable to the claimed invention "because the teaching is directed to induction of an immune response in mice instead of dogs." This is **not** what was argued. Rather, what was argued that the reference teaches establishment of an immune response to a non-metastatic cell line (incidentally in a mouse model), while the present invention relates to treatment of a highly invasive form of melanoma that occurs in dogs. Thus, the distinction that Applicants are making is between a highly invasive, and generally fatal real world disease, and a substantially benign model system.

The Examiner also continues with the argument that Zhai has something to do with a metastatic melanoma. In this regard, she points to the reference to metastatic melanomas in the abstract. It is noted, however, that while this may have been the intended purpose of the vaccines that were to ultimately be made as a follow-on to Zhai's research, there is no actual testing with a metastatic cell line, and nothing that relates to the highly aggressive CMM that is recited in the claims of this application.

In this regard, the Examiner appears to be confused about the relationship of genus and species. For example, on Page 6 of the Examiner's Answer, the statement is made that "the metastatic melanoma of Zhai is within the scope of CMM." This is backwards. Zhai broadly refers to metastatic melanomas and then tests a non-metastatic system. CMM is one type of metastatic melanoma which has proven to be extremely resistant to treatment. Unless the Examiner is asserting (without evidentiary support) that cancer is so predictable that one set of tests in a benign tumor model can provide an expectation that the method will work in all cancers of the same type, regardless of the degree of invasiveness¹ then the failure to consider CMM as a distinct species, for which a genus disclosure is not automatically relevant if a fatal flaw in the rejection.

Finally, Applicants note that while claim 30 was argued separately in the Appeal brief, the Examiner has utterly failed to address this argument in the Reply Brief. As previously noted, Claim 30 is dependent on claim 20, and recites the additional limitation that

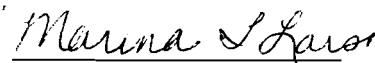
the xenogeneic differentiation antigen is administered by DNA immunization of the subject with DNA encoding the xenogeneic differentiation antigen in a **non-viral plasmid vector** comprising DNA encoding the xenogeneic differentiation antigen under the control of a promoter which promotes expression of the xenogeneic differentiation antigen.

Thus, this claim differs further from the teaching of Zhai et al in the nature of the vector being employed, since Zhai et al use an adenoviral vector. This difference is of patentable significance and the Examiner has provided no response to the contrary.

¹ This argument, if made, would run counter to the position taken by the vast majority of PTO Examiner's concerning the predictability of cancer therapy and therefore really should be substantiated and expressly stated in writing.

Accordingly, Applicants again submit that the rejection is in error, and that it should be reversed.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Marina T. Larson".

Marina T. Larson Ph.D.
PTO Reg. No. 32,038
Attorney for Applicant
(970) 262 1800